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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,270	11/07/2001	C.J. Anthony Fernando	01-22 US	3025
23693	7590	11/24/2003	EXAMINER	
Varian Inc. Legal Department 3120 Hansen Way D-102 Palo Alto, CA 94304			GAKH, YELENA G	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/014,270

Applicant(s)

FERNANDO ET AL.

Examiner

Yelena G. Gakh, Ph.D.

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-40, drawn to a manifold device, classified in class 422, subclass 36.
  - II. Claims 41-45, drawn to a method for measuring an analyte, classified in class 436, subclass 52.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method can be performed for one flow cell.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Bella Fishman on 10/16/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-40. Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 8 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites in subparagraph (b), "the first fiber-optic end optically aligned with the light-reflective surface", and in subparagraph (c), "the second fiber-optic end optically aligned with the light-reflective surface". It is not clear, what the expression "optically aligned with the light-reflective surface" means; it is further unclear what type of "light-reflective surface" is considered here, since the specification does not support such terminology. The expression used in claim 6 renders it unclear and indefinite.

Claim 8 recites in subparagraph (f), "each optical fiber output line communicating ... in opposing, optically-aligned relation to the optical fiber input line", which is not a clear expression and is not supported by the specification. Clarification of the claim language is required.

Claim 20 recites, "each first fiber-optic end is disposed in spaced, optical alignment with its corresponding second fiber-optic end". It is not apparent, what this expression means. It is not clear, how "the first fiber-optic end" can have "its corresponding second-fiber end", when these ends belong to different optical fiber lines - input and output, respectively. Clarification of the claim language is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1743

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 1-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins et al. (US 6,060,024, IDS) in view of Roinestad et al. (US 6,174,497 B1, IDS).

Hutchins discloses "a dissolution testing system including a base; a plurality of vessels mounted on the base; an agitation mechanism for agitating a liquid content of the vessels; and a head supported above each of the vessels and operable to automatically inject a liquid media into the vessel (Abstract). "The sampling lines 17 are connected to the inlets of the sampling pumps 13, the outlets of which communicate through the filters 98 with either an external six cell UV analyzer 115 or the inlets of a multiple port valve 116. Outlets of the valve 116 communicate either with the waste manifold 97 or an external valve 118 alternatively feeding either a UV analyzer 121, an HPLC system 122 or a fraction collector 123" (col. 4, lines 13-19). Six cells are placed in a unitary cells manifold.

Hutchins does not disclose a plurality of probes comprising optical fiber input and output lines going through the flow cells with the light path formed by the inlet and outlet optical fiber lines transverse to the flow through the flow cells.

Roinestad discloses "detection systems and methods for predicting the dissolution curve of a drug from a pharmaceutical dosage form" (Title). In one of the embodiments he indicates, "UV radiation is transmitted from the source lamp through the fiber (which extends into the probe) and through a quartz lens seated directly above the flow cell. UV radiation travels through the flow cell and is reflected off a mirror positioned at the terminal end of the probe. The radiation then travels back through the flow cell and quartz lens. It is directed into a second fiber where it travels to the spectrometer for analysis. Quantitation of the drug substance is accomplished by determining the change in intensity of UV radiation as it is transmitted through the flow cell" (col. 7, lines 24-33). In one of the embodiments the software "may provide comparative analysis to reference standards" (col. 8, lines 37-38), which inherently includes measurements taken for the reference solutions (blank or standards).

Art Unit: 1743

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-3 and 5-6** are rejected under 35 U.S.C. 102(3) as being anticipated by Fry et al. (US 6580507 B2).

Fry discloses a manifold device for use in sample measurements comprising: a manifold body (10) defining a plurality of flow cells therein; a plurality of liquid input and output lines (4 and 4') in communication with the plurality of cells (Fig. 2a); a plurality of probes comprising input (19, Fig. 1c) and output (15, Fig. 1b) optical fiber lines communicating with the cells, with the optical path through the corresponding flow cell generally transverse to the liquid flow path (col. 7, lines 53-60 and col. 8, lines 9-15 and 19-24).

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1743

It would have been obvious for anyone of ordinary skill in the art to slightly modify Hutchins by substituting six cells in UV analyzer with the flow cells provided with the fiber optical probes, as disclosed by Roinsted, because it gives more flexibility in varying test parameters, such as the number of flow cells required for simultaneous measurements of multiple solutions, which is not restricted by the number of cells provided by UV spectrometer. The diameters of the input and output fiber optical lines (equal or different) are easily adjustable for getting the most accurate results.

It would have been obvious for anyone of ordinary skill in the art to include a distribution mechanism between plurality of the vessels with samples and calibration (blank or standard) solutions and the flow cells in order to provide calibration for each sample solution, if necessary.

It would have been obvious to at least partially return the calibration liquids back into the vessels in order to prevent losses of the calibration solutions through the return lines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh  
11/21/03

